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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,618

03/01/2004

Antonius Franciscus Wilhelmus van der Steen

2183-6375US

8842

72286

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LEYDIG, VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 N. STETSON  
CHICAGO, IL 60601-6731

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/790,618	<b>Applicant(s)</b> VAN DER STEEN ET AL.	
	<b>Examiner</b> Brian Szmal	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/06; 9/19/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to Claims 1 and 2, the use of “which” renders the claims indefinite. With regards to Claims 2, 7, 12 and 14, the use of “practically” renders the claims indefinite. With regards to Claim 12, “the tissue is an artery moving through the heartbeat” renders the claim indefinite since it is unclear how an artery can move through a heartbeat. Furthermore, with regards to Claim 12, “this direction” is indefinite since it is unclear which direction is being claimed.

3. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

With regards to Claim 2, “correlating signals consecutive over time, which signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other” is unclear to the Examiner. With regards to Claim 14, “correlation detection means for detecting the correlation between consecutive signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other” is unclear to the Examiner.

4. Claim 10 recites the limitation "the motion" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 6-8, 11, 13, 14, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1).

Torp et al disclose a means for real-time calculation and display of strain in ultrasound imaging and further disclose receiving signals from a tissue with a sensor for measuring the deformation of the tissue in a measuring plane defined by the sensor, the sensor during a varying pressure exerted on the tissue; identifying strain of the tissue from the signals received by the sensor; relating the strain to at least one of either hardness or elasticity; correlating signals consecutive over time, the signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other; calculating by means of the correlating step, strain in a tissue surface or tissue volume part; displaying elasticity or hardness parameters of a tissue surface or tissue volume part; the signals are echographic data detected with an acoustic sensor; displaying elasticity or hardness parameters of the

tissue with position information of the sensor or tissue; signals possessing an overlap are received; a processor for collecting and processing signals from the sensor to identify strain of the tissue and to relate strain to elasticity or hardness parameters of a tissue surface or tissue volume part; a first activating means for activating data storage; and the activating means are connected with the correlation detection means to become active at a predetermined correlation. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; and Column 8, lines 8-17.

Torp et al however fail to disclose moving the sensor along the tissue in a direction transverse to the measuring plane; the signals are received during practically continuous motion of the sensor; the signals come from a blood vessel wall and the data is received only during a specific time period; the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter.

Porat et al disclose a means for tissue characterization and further disclose moving the sensor along the tissue in a direction transverse to the measuring plane; the signals are received during practically continuous motion of the sensor; the signals come from a blood vessel wall and the data is received only during a specific time period; the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a

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catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter. See Paragraphs 0286 and 0298.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability to move the sensor along a blood vessel, as per the teachings of Porat et al, since it would provide a means of determining a tissue parameter along a length of tissue.

7. Claims 5, 10, 12, 15-17, 19, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1) as applied to claims 1 and 13 above, and further in view of Panescu et al (5,848,969).

Torp et al and Porat et al, as discussed above, disclose a means for measuring a tissue parameter along a length of a blood vessel but fail to disclose the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time intervals in the period of the motion; the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery; a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat.

Panescu et al disclose a means for visualizing internal structures and further disclose the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time intervals in the period of the motion; the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery; a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat. See Column 3, liens 59-67; Column 4, liens 1-5; Column 6, liens 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, liens 21-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to control the movement of the sensors, as per the teachings of Panescu et al, since it would provide a means of accurately measuring a tissue parameter along a length of tissue.

***Allowable Subject Matter***

8. Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/  
Primary Examiner, Art Unit 3736